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INTERNATIONAL SEARCH REPORT

Int'l application No.
PCT/GB 97/02626

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery or therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 97/02626

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-14

Member (=patch) being suitable for placing in contact with the skin and being pierceable by stream of injectate

2. Claims: 15-22

Device comprising means for indexing the patches successively to a location adjacent the site to be injected

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati Application No

PCT/GB 97/02626

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9504511 A	16-02-95	AU 7009994 A	28-02-95
FR 2625438 A	07-07-89	NONE	
EP 613670 A	07-09-94	BR 9400769 A	11-10-94
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		JP 2232047 A	14-09-90
US 2764934 A	02-10-56	NONE	
US 3745083 A	10-07-73	NONE	



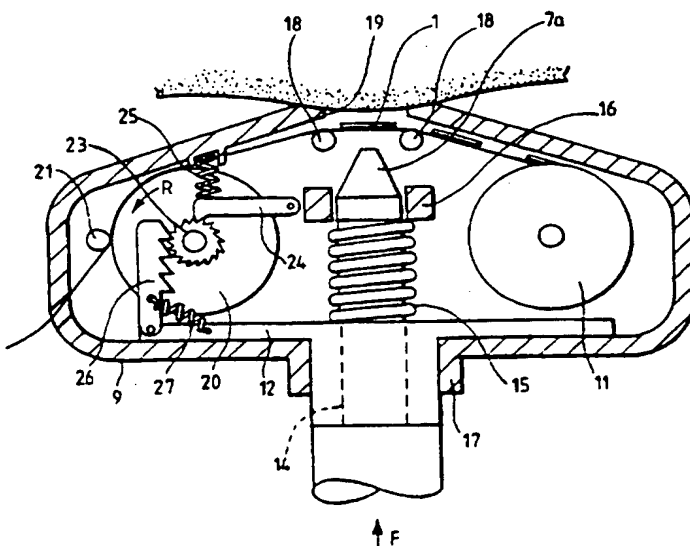
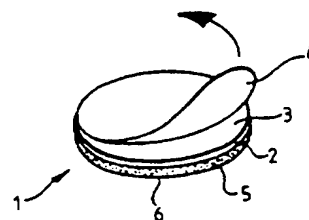
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 2 April 1998 (02.04.98)
(21) International Application Number: PCT/GB97/02626		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW. ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
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(71) Applicant (for all designated States except US): WESTON MEDICAL LIMITED [GB/GB]; 2a Hales Barn Workshops, New Street, Stradbroke, Eye, Suffolk IP21 5JG (GB).			
(72) Inventors; and (75) Inventors/Applicants (for US only): WESTON, Terence, Edward [GB/GB]; Thornlea, Pixey Green, Stradbroke, Eye, Suffolk UP21 5NG (GB). EMMOTT, Douglas, Arthur [GB/GB]; 3 Hedgerow Cottages, Pettaugh Lane, Gosbeck, Suffolk IP9 6SD (GB).			
(74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).		<p>Published Without international search report and to be republished upon receipt of that report.</p>	

(54) Title: NEEDLELESS INJECTOR ACCESSORY

(57) Abstract

A patch, or continuous piece of material, is described for use in needleless injection of a stream of injectate through the skin of a subject. In the case of the patch, this is adhered to the skin of the subject prior to injection, and injection takes place through the patch, which is pierced by the stream of injectate. The patch remains temporarily adhered to the skin after injection to provide protection.



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NEEDLELESS INJECTOR ACCESSORY

This invention relates to an accessory for use in the needleless injection of a stream of injectate through the skin of a subject.

Needleless injectors are used as an alternative to needle-type hypodermic syringes for delivering liquid drugs and medicaments directly through the patient's skin and into the tissues without using a hollow needle. Such injectors consist of a piston pump driven by a spring or pressurised gas, which ejects the liquid drug or medicament through a small discharge orifice at a sufficient rate and pressure to pierce the skin and enter the tissues through the hole thus formed.

Such injectors have been known for over fifty years, and, until recently, multi-dose injectors were a common device for vaccinating large numbers of people economically. However, with the advent of AIDS, and the increase in other highly infectious diseases such as hepatitis B, it was found that such multi-dose injectors could pick up infectious body fluid from one patient and transfer it to the next. This occurred as the result of the nozzle and its surrounding structure touching the skin: either infectious fluid already on the skin or a slight reflux of infectious blood through the injection hole in the skin would be sufficient to contaminate the nozzle. Consequently, multi-dose injectors are now hardly used except in veterinary applications. Nevertheless, such injectors have the lowest cost per dose of any parenteral delivery system, and there have been attempts recently to provide injectors which have the drug delivered from a disposable capsule attached manually to the injector. However, when vaccinating large numbers of people, such methods can be inconvenient, and they certainly add to the cost.

According to the present invention there is provided a member for use in needleless injection of a stream of injectate through the skin of a subject, said member being suitable for placing in contact with the skin during injection and being piercable by the stream of injectate when delivered thereto at pressure such that after passage through the member it is at a pressure suitable for passage through the skin.

The member is preferably in the form of a self adhesive patch formed of a thin plastics material. Needleless injectors may be designed to have ample power to pierce such a patch without detriment to the injection efficiency. Preferably, the

patch material is substantially self-sealing immediately after the injection, i.e. the hole produced in the patch by the injection has a tendency to close up and prevent reflux of injectate and/or blood. Optionally, the patch material may be coated or impregnated with a disinfectant, anti-bacterial material, or other anti-infection material.

The advantage of the injection patch is that each patient's skin is covered before contact with the injector nozzle, and there is thus no contamination of the nozzle. After the injection, the patch material closes the wound to prevent oozing of the fluid. If required, the patch may include an absorbent layer, or the patch material itself may be absorbent, so as to further reduce the chance of contaminating the injector nozzle. After the injection, the patch is left in place for a short time until the injectate has dispersed somewhat within the tissues. This has the added advantage that scratching of the infection site is prevented whilst the patch is in place. This is similar to the recommended practice of holding a sterile swab in place after any type of injection.

The patches may be applied by the patients or by an assistant, or automatically by a device attached to the injector. If the patches are applied some minutes prior to the injection, the outer surface is preferably protected from contamination by a tamper-evident film, which is removed immediately before the injection. The patches may be releasably pre-assembled onto a carrier strip, and protected by a further strip or individual cover, the whole being sterilised.

An alternative to using individual patches is to use a continuous strip of material which may be automatically indexed past the nozzle to protect it for each injection. This, however, does not have the advantage of continuing the protection of the injection site for a short time after the injection.

The invention will now be further described by way of example, with reference to the accompanying drawings in which:

Figure 1 is a perspective view showing a member in the form of a patch;

Figure 2 is a diagrammatic representation of a continuous strip of patches;

Figure 3 is a perspective view of a needleless injector fitted with a cartridge for feeding patches automatically;

Figure 4 is a cross-section through the cartridge of Figure 3, and showing also

part of the needleless injector of Figure 3 prior to firing; and

Figure 5 is a view corresponding to Figure 4 but showing the injector as it is fired.

Referring first to Figure 1, patch 1 comprises a flexible, skin-protecting film 2 preferably formed of a suitable plastics material such as polyethylene or a self-sealing material sold under the Trade Mark PARAFILM. The film 2 has a surface 3 which, in use, is contacted by the needleless injector, and this surface is covered prior to use by a peel-off protective film 4 which also acts as a tamper-evident layer. The surface of the skin-contacting film 2 which is on the other side of the film to the surface 3 is coated with a layer of adhesive 5, which in turn may be protected by a removable release film 6. The adhesive 5 is selected to be suitable to be adhered to the patient's skin. Often there is a small reverse flow of medicament after an injection, and to allow for this the skin-contacting film 2 may be absorbent and anti-bacterial (or anti-infection in some other way), or may have a layer of material thereon which is absorbent and anti-infection.

Preferably, the colour of the protective film 4 is different to that of the skin-contacting film 2, or it is visually distinguishable in some other way, for example by giving it a pattern, e.g. of stripes, to enable immediate recognition that the film has been removed and the sterile surface is exposed.

The patch is used by removing the release film and sticking the patch to the patient's injection site. Immediately before the injection is given, the protective film 4 is removed. The injector nozzle is pressed against the skin-contacting film 3 and the injectate is fired through that film and through the adhesive layer 5. Preferably the film 3 and the adhesive layer 5 are integrated with one another to a sufficient extent to ensure that there is no possibility of small pieces of film 3 or adhesive 5 being torn away and injected into the patient.

Figure 3 shows a multi dose injector 7 with a cartridge 8 removably attached to the injection end thereof, so as to enable a plurality of injections to be given successively, each through a respective patch applied automatically to the skin of the patient. The injector 7 has an injection nozzle 7a (see Figures 4 and 5). The cartridge 8 is shown in more detail in Figure 4.

As can be seen in Figure 4, the cartridge 8 comprises a housing 9 within

which a carrier strip 10 having a plurality of patches 1 thereon is wound up on a reel 11. The cartridge 8 has a yoke 12 by means of which it is removably attached to the front end of the injector 7. To this end, the barrel 13 of the injector is fixedly mounted in a passageway 14 formed in the yoke 12. A compression spring 15 surrounds the barrel 13 and bears against the yoke 12 at one end and, at the other end, against an abutment 16 fixedly mounted with the casing 9. The yoke 12 is free to slide within a collar 17 which forms an extension from the main body of the casing 9.

As already mentioned, the carrier strip 10, with the patches 1 carried thereon, is wound on a spool 11. The free end of the strip is threaded over support rollers 18 which are positioned either side of an opening 19 in the front of the casing. After passing over the rollers 18 the strip passes over a drive wheel 20 and through a nip formed between the drive wheel 20 and a pinch roller 21. The latter keeps the strip in frictional contact with the surface of the drive wheel, so that when the drive wheel rotates in the direction of the arrow R, by the means described below, the carrier strip is pulled from the spool. After leaving the nip between the drive roller 20 and pinch roller 17 the strip exits the cartridge through an opening 22.

The drive wheel 15 has a toothed wheel 23 mounted coaxially thereon for rotation therewith. A pawl 24 is urged into engagement with the toothed wheel 23 by a compression spring 25, and a rack 26, pivotally mounted on the yoke 12, is also urged into contact with the toothed wheel 23, this time by means of a tension spring 27 acting between the rack and the yoke. The manner of operation of these components will become apparent from the ensuing description of the operation of the device.

When the device is to be used the front of the cartridge 8 is placed on the patient's skin 28, with the opening 19 opposite the intended injection site. Assuming that a patch 1 is already located opposite the opening 19, as shown in Figures 4 and 5, the injector 7 is pushed towards the patient's skin 28 in the direction of the arrow F, which causes the yoke 12 to move in the same direction, from the position shown in Figure 4 to that shown in Figure 5. This compresses the spring 15. The nozzle 7a of the injector 7 presses against the patch located opposite the opening 19, which is thereby pressed onto the skin 28, and the injector is operated at this point and the

injectate is fired through the patch and into the patient's tissues. During this part of the procedure, the pawl 24 prevents movement of the drive wheel 20. It is greatly preferred that the injector should operate automatically on reaching the optimum skin contact force, and an injector which operates in this manner is described in PCT published application WO 93/03779, to which attention is directed for further details.

The patch becomes detached from the carrier strip 10 as a result of the above-described operation, and remains adhered to the patient's skin after removal of the injector nozzle 7a, thus providing short-term protection for the wound, and containing any reflux of injectate. After the injector is removed, spring 15 returns the cartridge 8 to the position shown in Figure 4, and the rack 26 indexes the drive wheel 20 in the direction of arrow R to move the next patch into position for application.

Figure 2 is a diagram showing the structure of an embodiment of carrier strip 10, with patches 1, for use in the device described above. It will be seen that the carrier strip comprises a film 30, with a release film 31 on one face thereof, to prevent the patch adhesive 5 (see below) from sticking to the film 30 when the strip is rolled up, and adhesive 32 on the opposite face. The patches are secured to the strip by means of the adhesive 32. Each patch 1 comprises a skin-contacting film 2 and adhesive 5, as in the case of the patches shown in Figure 1, and on the face adjacent the carrier strip 10 each patch has a release film 33 to enable it to detach itself readily from the carrier strip after injection.

CLAIMS:

1. A member for use in needleless injection of a stream of injectate through the skin of a subject, said member being suitable for placing in contact with the skin during injection and being piercable by the stream of injectate when delivered thereto at pressure such that after passage through the member it can pass through the skin.
2. A member according to claim 1, which is in the form of a patch.
3. A member according to claim 2, comprising a flexible film having first and second faces.
4. A member according to claim 2, having adhesive by which, in use, it can be adhered to the skin.
5. A member according to claim 3, having adhesive by which, in use, it can be adhered to the skin, the said adhesive being on the first face of the flexible film.
6. A member according to claim 5, comprising a removable release layer covering the adhesive prior to use.
7. A member according to claim 3, 5 or 6, wherein the said second face of the flexible film is covered by a removable protective layer prior to use.
8. A member according to claim 7, wherein the said removable protective layer is distinguishable from the said flexible film, so as to give ready identification of removal of the protective layer.
9. A member according to claim 1, which is in the form of an elongate strip having a length such that a respective segment of the strip can be placed in contact with the skin of a respective one of a plurality of successive subjects.

10. A member according to any preceding claim, of a material which is self-sealing after the injection.
11. A member according to any preceding claim, capable of absorbing liquid from the location where it is in contact with the skin.
12. A member according to any preceding claim, having anti-bacterial or other anti-infection properties.
13. A plurality of patches according to any one of claims 2 to 8, or any one of claims 10 to 12 as dependent on any one of claims 2 to 8, carried by a carrier.
14. A plurality of patches according to claim 13, wherein the carrier is an elongate strip.
15. A device for enabling a needleless injector to dispense each of a plurality of successive doses of an injectate through a respective one of a plurality of patches according to claim 14, comprising means for indexing the patches successively to a location on the device adapted to be disposed adjacent the site to be injected, and means for receiving the injector so as to align an outlet orifice thereof with the patch at the said location, whereby to permit injection through the said patch.
16. A device according to claim 15, wherein the said receiving means permits movement of the injector towards the said location, to effect injection, and away from it, the device comprising means for indexing a fresh patch to said location in response to the said movement.
17. A device according to claim 16, comprising means for biasing the injector away from said location.
18. A device according to any one of claims 15 to 17, wherein an elongate strip, with unused patches thereon, is held on a reel.

19. A device for enabling a needleless injector to dispense each of a plurality of successive doses of an injectate through a respective area of an elongate strip, comprising means for indexing successive areas of the strip to a location on the device adapted to be disposed adjacent the site to be injected, and means for receiving the injector so as to align an outlet orifice thereof with the strip area at the said location, whereby to permit injection through the said area.
20. A device according to claim 19, wherein the said receiving means permits movement of the injector towards the said location, to effect injection, and away from it, the device comprising means for indexing a fresh area of the strip to said location in response to the said movement.
21. A device according to claim 20, comprising means for biasing the injector away from said location.
22. A device according to any one of claims 19 to 21, wherein the elongate strip is held on a reel.
23. A method for needleless injection of injectate through the skin of a subject, wherein injection takes place through a member according to any one of claims 1 to 12.

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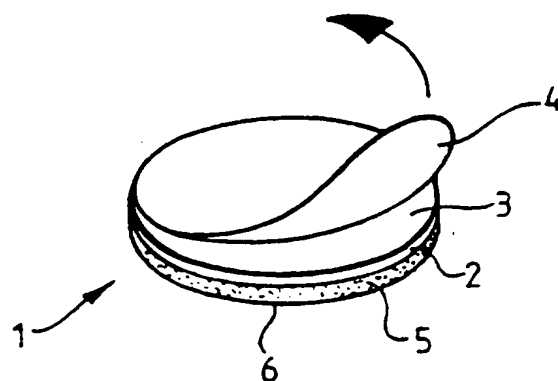


Fig.1.

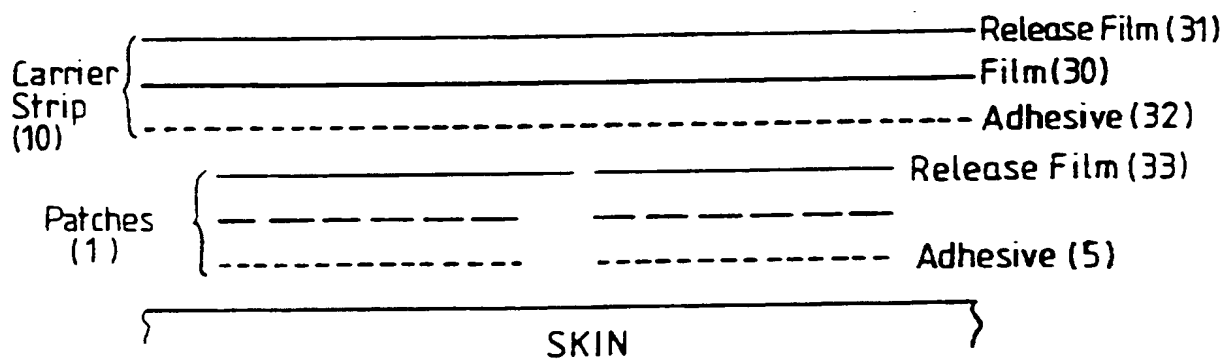


Fig.2.

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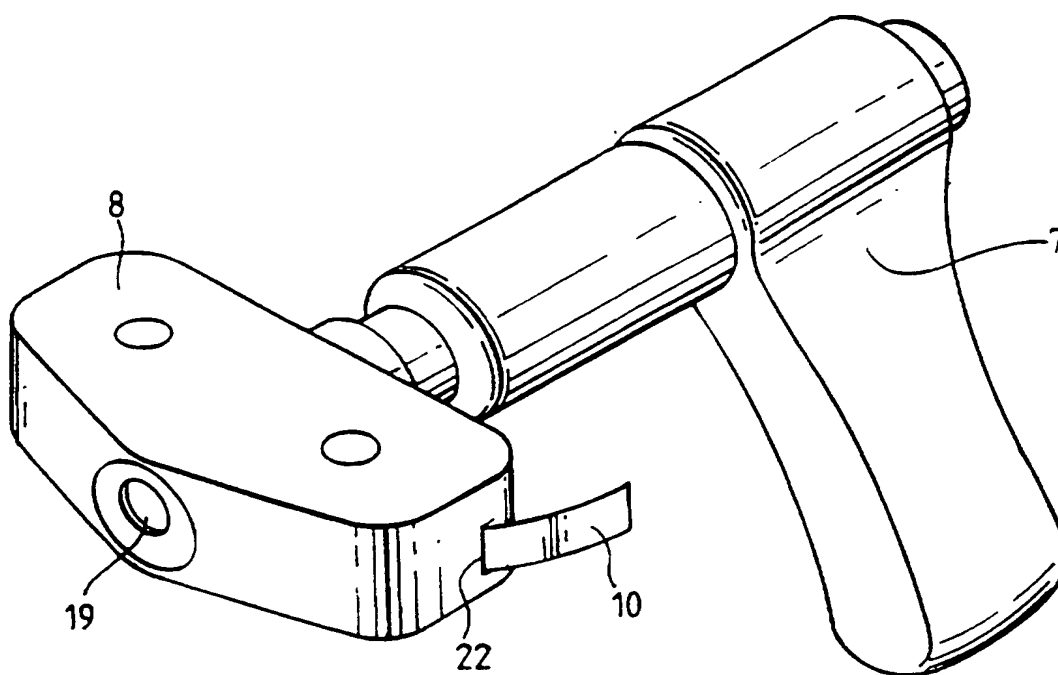
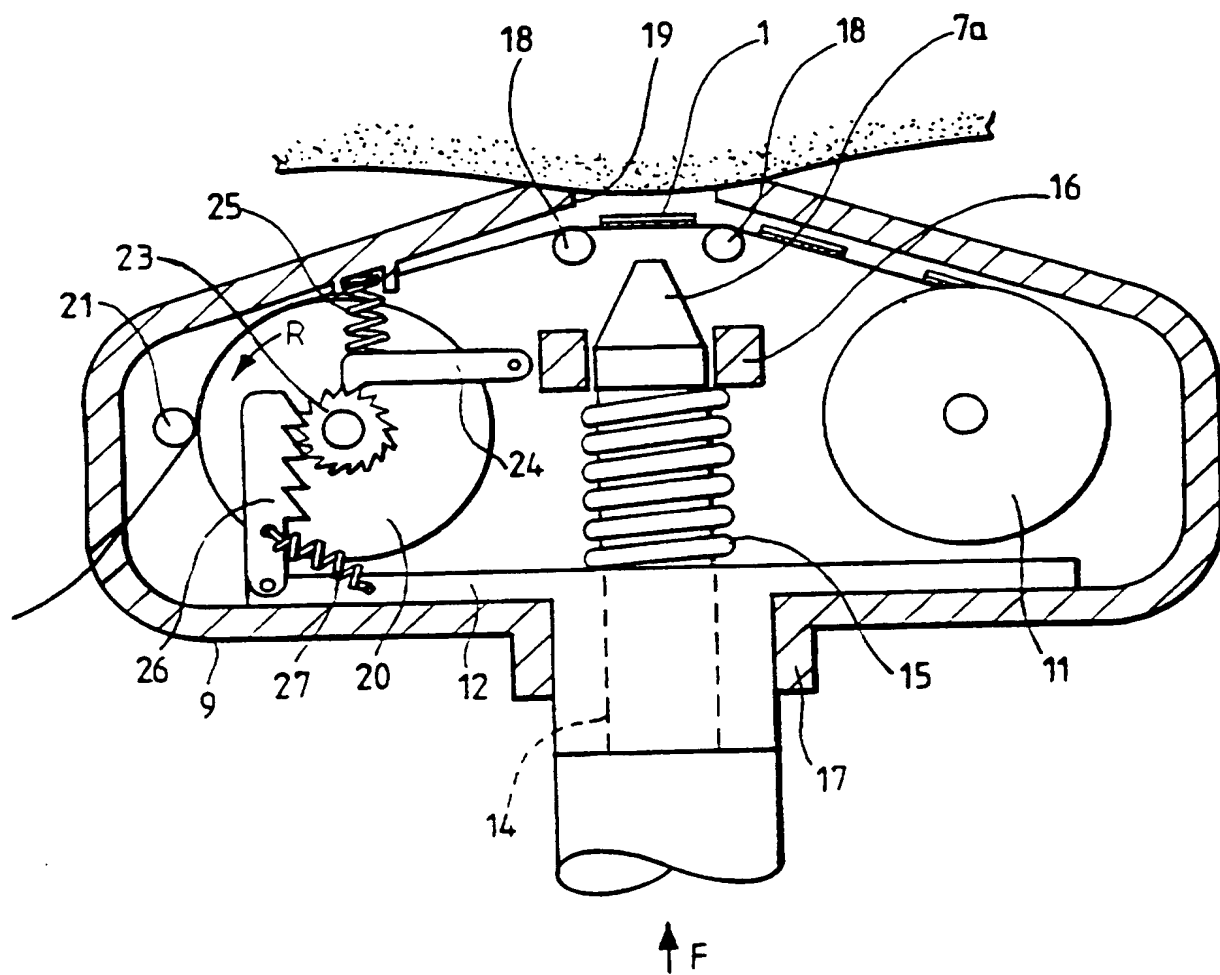
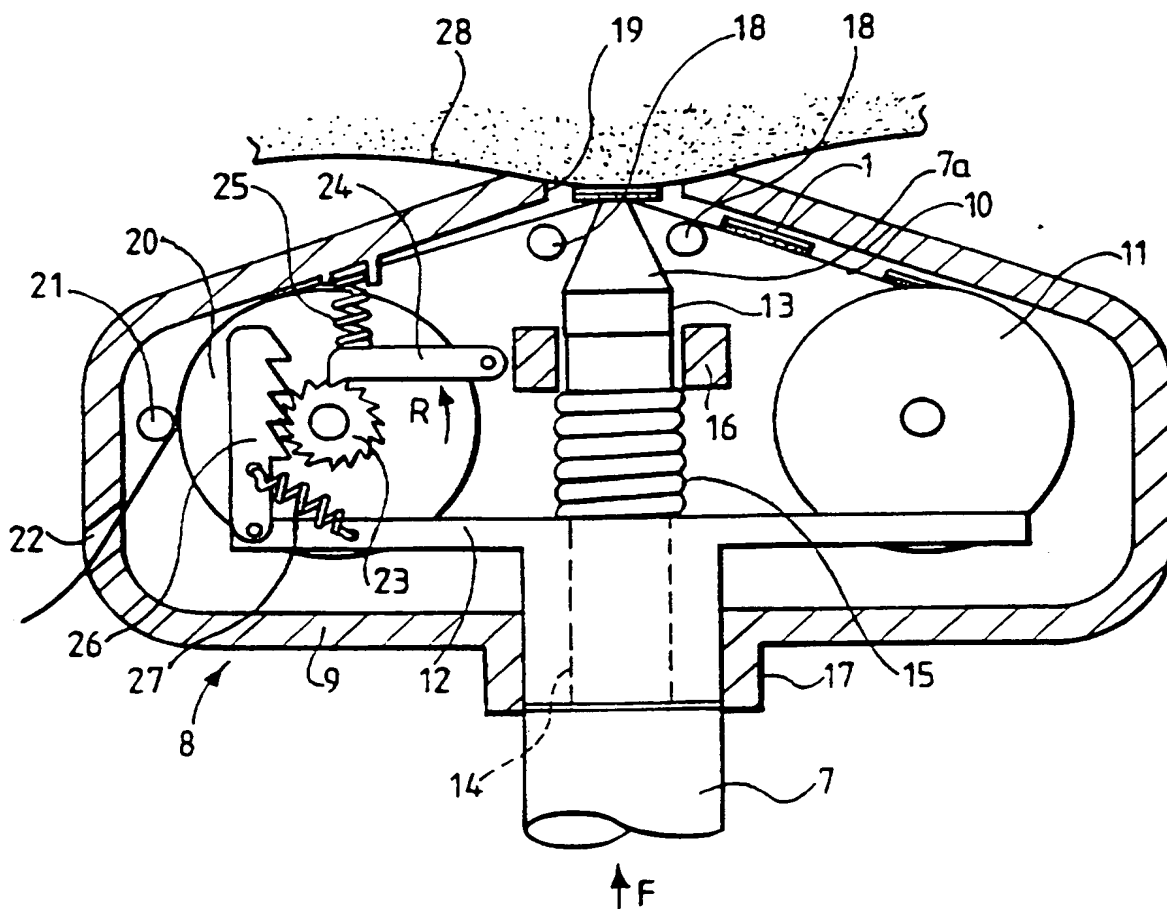


Fig.3.

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*Fig.4.*

4/4

*Fig.5.*

INTERNATIONAL SEARCH REPORT

Internatic Application No

PCT/GB 97/02626

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/30 A61F13/02 A61M5/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61F B65C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	* Relevant to claim No.
X	WO 95 04511 A (SMITH) 16 February 1995 see page 1, line 3 - line 11 see page 4, line 22 - line 33 see page 4, line 6 - line 14 ---	1-7, 10-12
X	FR 2 625 438 A (C.E.D.I.A.T. - MEDIFFUSION) 7 July 1989 see page 3, line 29 - line 37 ---	1-7, 10-12
A	EP 0 613 670 A (JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.) 7 September 1994 see column 3, line 15 - line 27 see figure 3 ---	9
A	EP 0 368 264 A (HOLZER) 16 May 1990 see abstract; figure 3 ---	1
-/-		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 764 934 A (KAPLAN) 2 October 1956 see column 2, line 56 - column 3, line 27 see figures ---	15,16, 19,20
A	US 3 745 083 A (AUNGST ET AL.) 10 July 1973 see column 8, line 33 - line 55 see figures 1-4 -----	15,16, 19,20